

Development and Validation of Analytical Method for Simultaneous Estimation of Azithromycin and Levofloxacin in Bulk and its Dosage Form

Submitted By

VARIA NIRAV CHANDRAKANTBHAI

Supervised By:

Mrs. Pinkal Patel

M.Pharm, Assistant Professor, Department of Quality Assurance

Parul Institute of Pharmacy and Research

Limda, Ta. Waghodia, Dist. Vadodara 391760

ABSTRACT

A simple, accurate and precise UV Spectrophotometric methods and RP-HPLC method was developed and validated for simultaneous estimation of Azithromycin and Levofloxacin in bulk and tablet dosage form. For UV spectrophotometry Q absorption Ratio method was developed. In Q-absorption ratio method determination was carried out at 218.4 nm λ_{max} of Azithromycin and 224.4 nm an Iso-bestic point of both the drug. The linearity range lies between 10-60 $\mu\text{g/ml}$ for Azithromycin and 4-24 $\mu\text{g/ml}$ for Levofloxacin at their respective wavelengths. Both the drugs were found in good agreement with the label claimed in the marketed formulation. In the tablets both the drugs were estimated as 100.39% and 99.94% of Azithromycin and Levofloxacin respectively. The RP-HPLC method for simultaneous estimation of Azithromycin and Levofloxacin. The separation was achieved on a Xterra RP₁₈ (150mm X 4.6 mm i.d., 5 μm particle size) with an isocratic mixture of acetonitrile: water: dipotassium

hydrogen phosphate buffer (pH 6.5) adjusted with ortho-phosphoric acid in the ratio of 35:55:10 v/v. The mobile phase at a flow rate of 1.0 ml/min, Injection volume 10 μ l and wavelength of detection was kept at 215 nm. The retention time Azithromycin and Levofloxacin was 7.43 ± 0.03 and 2.21 ± 0.02 respectively. The linearity of a simple, accurate, precise RP-HPLC method was developed and validated for simultaneous estimation of Azithromycin and Levofloxacin in bulk and tablet dosage form. The proposed method was investigated in the range of 20-120 μ g/ml for both, Azithromycin and Levofloxacin, respectively. Correlation coefficient was 0.999 and 0.999 for Azithromycin and Levofloxacin, respectively. The limit of detection was 0.07 μ g/ml and 0.042 μ g/ml for Azithromycin and Levofloxacin, respectively and the limit of quantification was 0.20 μ g/ml and 0.112 μ g/ml for Azithromycin and Levofloxacin, respectively.

Keywords: Azithromycin, Levofloxacin UV Spectroscopic method ,Q-Abasorption ratio method and RP-HPLC